

## § 422.516

## 42 CFR Ch. IV (10–1–24 Edition)

same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 83 FR 16734, Apr. 16, 2018; 85 FR 33908, June 2, 2020; 88 FR 22334, Apr. 12, 2023; 89 FR 30824, Apr. 23, 2024; 89 FR 79451, Sept. 30, 2024]

### § 422.516 Validation of Part C reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the provider-patient relationship, information with respect to the following:

- (1) The cost of its operations.
- (2) The procedures related to and utilization of its services and items.
- (3) The availability, accessibility, and acceptability of its services.
- (4) To the extent practical, developments in the health status of its enrollees.
- (5) Information demonstrating that the MA organization has a fiscally sound operation.
- (6) Other matters that CMS may require.

(b) *Significant business transactions.* Each MA organization must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

- (1) A description of significant business transactions (as defined in § 422.500) between the MA organization and a party in interest.
- (2) With respect to those transactions—
  - (i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or
  - (ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.
- (3) A combined financial statement for the MA organization and a party in

interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the MA organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the MA organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the MA organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an MA organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an MA organization in its offerings, the MA organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular MA organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The MA organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each MA organization must make the information reported to CMS under § 422.502(f)(1) available to its enrollees upon reasonable request.

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine